Food and Drug Administration

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee Meeting
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD

March 20, 2012

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Caleb Briggs, Pharm.D.

Division of Advisory Committee and Consultant Management Office of Executive Programs Center for Drug Evaluation and Research

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Deborah K. Armstrong, M.D.

Associate Professor of Oncology
The Sidney Kimmel Comprehensive Cancer
Center at Johns Hopkins
The Johns Hopkins University School of
Medicine
Baltimore, Maryland

Frank Balis, M.D.

The Louis and Amelia Canuso Family Endowed Chair for Clinical Research in Oncology The Children's Hospital of Philadelphia University of Pennsylvania School of Medicine Philadelphia, Pennsylvania

Ralph Freedman, M.D., Ph.D.

Clinical Professor Department of Gynecologic Oncology The University of Texas M.D. Anderson Cancer Center Houston, Texas

Wm Kevin Kelly, D.O.

Professor, Medical Oncology and Urology Director, Division of Solid Tumor Oncology Associate Director, Translational Research Thomas Jefferson University Philadelphia, Pennsylvania

Brent Logan, Ph.D.

Professor of Biostatistics Division of Biostatistics Medical College of Wisconsin Milwaukee, Wisconsin

Mikkael Sekeres, M.D., M.S.

Associate Professor of Medicine Staff, Cleveland Clinic Taussig Cancer Institute Department of Hematologic Oncology and Blood Disorders Cleveland, Ohio

Wyndham Wilson, M.D., Ph.D. (Chairperson)

Chief, Lymphoma Therapeutics Section Metabolism Branch Center for Cancer Research National Cancer Institute (NCI) National Institutes of Health (NIH) Rockville, Maryland

Jane Zones, Ph.D. (Consumer Representative)

Medical Sociologist (retired) Breast Cancer Action National Women's Health Network San Francisco, California

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DRAFT MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE ONCOLOGIC DRUGS ADVISORY COMMITTEE

(Non-Voting)

Howard Fingert, M.D., F.A.C.P.

(Acting Industry Representative)
Senior Medical Director, Clinical Intelligence
Millennium, the Takeda Oncology Company

Cambridge, Massachusetts

TEMPORARY MEMBERS (Voting)

Aman U. Buzdar, M.D. (Afternoon Session Only)

Vice President Clinical Research and Interim Professor of Medicine M.D. Anderson Cancer Center Dept. of Breast Medical Oncology Houston, Texas

Ephraim Casper, M.D.

Head, Division of Network Medicine Services Department of Medicine Memorial Hospital Memorial Sloan-Kettering Cancer Center New York, New York

Lee J. Helman, M.D.

Scientific Director for Clinical Research Center for Cancer Research National Cancer Institute (NCI) National Institutes of Health (NIH) Bethesda, Maryland

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Associate Professor of Pediatrics Keck School of Medicine/University of Southern California Director -Clinical Trials Office Children's Center for Cancer and Blood Diseases Childrens Hospital Los Angeles Los Angeles, California

Angela Myers, M.D., M.P.H. (Morning Session Only)

(Patient Representative)
Lenexa, Kansas

Kareem Shaya (Afternoon Session Only)

(Patient Representative)
Lutherville, Maryland

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DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, M.D.

Director, Office of Hematology and Oncology Products (OHOP), Office of New Drugs (OND), CDER, FDA

Robert Justice, M.D.

Director Division of Oncology Products 1 (DOP1), OHOP, OND, CDER, FDA

V. Ellen Maher, M.D. (Afternoon Session Only)

Medical Team Leader DOP1, OHOP, OND, CDER, FDA

Gwynn Ison, M.D. (Afternoon Session Only)

Medical Officer DOP1, OHOP, OND, CDER, FDA

Amir Shahlaee, M.D. (Morning Session Only)

Medical Officer DOP1, OHOP, OND, CDER, FDA

Lijun Zhang, Ph.D. (Morning Session Only)

Statistical Reviewer Division of Biostatistics V (DBV), Office of Biostatistics (OB), Office of Translational Science (OTS), CDER, FDA

<u>Huanyu (Jade) Chen, Ph.D. (Afternoon Session Only)</u>

Statistical Reviewer DBV, OB, OTS, CDER, FDA